REMARKS

Claims 1, 5-11, and 20-34 are pending in the present application. Claims 8-10, 22, 23, and 31-34 have been withdrawn. Claims 1, 21, and 28 have been amended in this paper. Reexamination and reconsideration of the application are respectfully requested.

The examiner objected to claims 21 and 28 regarding improper Markush language. In response thereto, applicant has amended claims 21 and 28 as suggested by the examiner.

The examiner rejected claims 1, 5, 6, 7, 11, 20, 21 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite. In response thereto, applicant has amended claim 1 to provide "an inflatable expandable member" and "below [[the]] a nominal inflation pressure" as suggested by the examiner. In view of the foregoing, all claims now fully comply with 35 U.S.C. § 112, second paragraph.

The examiner rejected claims 1, 5-7, 11, 20, 21 and 24 under 35 U.S.C. § 102(b) over Lenker et al. (U.S. Patent 5,843,158). This rejection is respectfully traversed.

The examiner relies on FIG. 4 of Lenker to teach an expandable membrane 78. Applicant respectfully notes that expandable membrane 78 is actually a balloon used at cuff 76 to block fluid flow through the expandable prosthesis, but is not used to expand the prosthesis. (See Lenker, col. 8, ll. 10-21.) However, Lenker does suggest that a balloon can be used to "to ensure full expansion of the liner from its compressed configuration." (Lenker, col. 8, ll. 31-34.)

Also, applicant has defined "nominal inflation pressure" in the specification, at p. 16, ll. 12-20. Applicant therefore respectfully disagrees with the examiner's interpretation of "nominal" to mean "small," which definition contravenes applicant's own definition in the specification. Rather, a first inflation pressure of the balloon is used

to cause the biocompatible material to fail, then the balloon is inflated to a higher nominal (second) inflation pressure to deploy the stent and implant the stent in the artery.

The examiner relies on col. 6, line 61 et seq. of Lenker to teach a reinforcement element 102. Applicant notes that Lenker, col. 6, line 61 et seq. describes a prosthesis 10, a tubular frame 12 made of individual non-connected ring frames 14, an inner liner 18, and an optional outer liner. There is no discussion of a reinforcement element used to restrict expansion of the endoprosthesis and which breaks when a sufficient expansion pressure is met. Rather, FIGS. 5B-5D and col. 9, ll. 36-59 of Lenker show and describe "reinforcement elements 102."

To better define the present invention, applicant has amended claim 1 to provide: "a biocompatible material ~~positioned on~~ tightly fitted over the endoprosthesis wherein the biocompatible material is entirely affixed to the endoprosthesis, the biocompatible material configured to prevent expansion of the endoprosthesis; wherein the biocompatible material is configured to fail at an inflation pressure below [[the]] a nominal inflation pressure of the expandable member." Support for the amendment is provided at page 4, ll. 24-25 and FIG. 10 of applicant's specification, for example.

As seen and described in Lenker at col. 9, ll. 36-59 and FIGS. 5B-5D, the reinforcement elements 102 are individually and at discrete points "adhesively bonded, welded, tied, riveted, integrally formed with, or otherwise attached to the frame." These attachment points are at opposite ends of a single "cell" 104 of the prosthesis as seen in FIGS. 5B-5D. In contrast, the reinforcement elements in the present invention is not individually anchored or affixed to the cells of the prosthesis, but rather the entire reinforcement filament is heat bonded to the underlying prosthesis (see FIG. 10 of applicant's specification, for example). At least for this reason, amended claim 1 and the other rejected claims are not anticipated by Lenker.

Regarding multiple balloon inflation pressures and at what pressure the reinforcement elements fail, Lenker appears to only contemplate one pressure. Lenker in

cols. 8-9 appears to only contemplate one inflation pressure used to break the reinforcement element, and does not teach or suggest first and second (nominal) inflation pressures, as recited in claim 1. Lenker for this reason does not anticipate the rejected claims.

The claimed invention is further not obvious in view of Lenker, because Lenker in the means of attachment of the reinforcement filament 102 to the prosthesis in FIGS. 5B-5D show individual points of attachment (see bulbous attachment points of reinforcement element 102 to wire stent struts 104 in FIGS. 5B-5D), and discrete tie down points in the FIG. 5E embodiment. Indeed, Lenker suggests in its list of attachment methods riveting or tying the reinforcement elements to the prosthesis struts, which processes are clearly based on discrete points of attachment. On the other hand, applicant claims the "biocompatible material is entirely affixed to the endoprosthesis" without need for discrete attachment points. Without discrete and individual attachment points, production is made much easier and reliability of individual attachment points need not be inspected. Also, use of individual attachment points in Lenker teaches away from the concept of attaching the entirety of the reinforcement element to the underlying prosthesis. At least for these reasons, claim 1 is not obvious in view of the cited reference.

As for the rejection of claim 7, applicant respectfully contends that "welding" as disclosed in Lenker is not heat bonding. Welding, as is understood in the art, requires that the base material of the prosthesis and the reinforcement element be heated such that both materials melt. In heat bonding, only one material, here presumably the plastic biocompatible material melts to the still solid metal prosthesis. Therefore, Lenker does not teach, suggest, or contemplate heat bonding.

The examiner rejected claims 25-30 under 35 U.S.C. § 103(a) over Lenker et al. in view of Kocur (U.S. Patent No. 6,350,277). This rejection is respectfully traversed.

Applicant has reviewed each of the passages cited by the examiner in Kocur but did not find any express or implied teaching regarding "wherein the heat bond fails

during expansion of the stent" recited in claim 25. In particular, Kocur in col. 6, line 5 describes as methods of attaching biodegradable material to a stent using heat or spot weld, but says nothing regarding failing *at those spot welds*; col. 4, line 18, describes using fatigue points that are a narrowed region of the stent retaining band; col. 5, line 18, describes using a web patch to cover a stent cell; col. 7, line 62, describes failure from mechanical failure or from degradation; so nothing expressly or impliedly in Kocur teaches a heat bond that fails under expansion pressure. Likewise, FIGS. 5a-5c, 10, and 11d of Kocur do not support the examiner's reading either. Since neither Kocur nor Lenker teaches or suggests "wherein the heat bond fails during expansion of the stent," the examiner has not established *prima facie* obviousness to support the rejection.

As for the examiner combining the two references, applicant respectfully contends that the examiner has not identified any motivation or desirability to combine or to modify the base reference Lenker with Kocur to support the rejection. Assuming *arguendo* Kocur teaches what the examiner alleges, Lenker only contemplated the reinforcement element breaking or failing without a failure at the point of attachment, it would not stand to reason that Lenker would be motivated to modify its teachings with Kocur so that the failures occurred at the attachment points and the base material. The modification lacks predictability since the failures could occur at an attachment point or in the base material, which would not be conducive to the precisely located and controlled expansion that Lenker was seeking in its prosthesis. (See, for example, Lenker, col. 10, ll. 10-11 "gradual (rather than incremental) expansion"; and col. 12, ll. 32-33, "controlled radial expansion of graft.") Therefore, it was improper for the examiner to combine the teachings of the two references. Applicant respectfully requests that the obviousness rejection be withdrawn.

Applicant respectfully disagrees with the other grounds of the examiner's rejections not specifically addressed above.

In view of the foregoing, all claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited.

Respectfully submitted,
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